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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/812,852	03/29/2004	Hadassa Degani	18801ZAZ	3443

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EXAMINER	
SUN, XIUQIN	
ART UNIT	**PAPER NUMBER**
2863	

DATE MAILED: 04/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/812,852	DEGANI, HADASSA
	Examiner	Art Unit
	Xiuqin Sun	2863

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *87-103 and 120-126* is/are pending in the application.

4a) Of the above claim(s) *1-86 and 104-119* is/are withdrawn from consideration.

5)☒ Claim(s) *92-101* is/are allowed.

6)☒ Claim(s) *87-91,102,103 and 120-126* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Per Applicants' response dated 02/28/06, a provisional election was made without traverse to prosecute Invention III of claims 87-103 and 120-126. Claims 1-86, 104-119 are withdrawn from further consideration by the Examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Objections

2. Claim 120 is objected to because of the following informalities:

Claim 120, line 5, the abbreviation "MRI" needs to be spelled out then followed by "(MRI)".

Appropriate correction is required.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claim 87 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 7 of U.S. Patent No. 6,553,327 to Degani (hereafter referred to as '327). Although the conflicting claims are not identical, they are not patentably distinct from each other because they are obvious variants of each other, as shown in Table 1 below.

Table 1

10/812,852	U.S. 6,553,327
87. A color coded image for use in evaluating a selected place in a system in which a fluid flows, and which is characterized by a change in the system with time in space as a function of a system parameter related to system wash-in behavior and wash-out behavior at two preselected time intervals after a system event, said image depicting in two or three dimensions an image of the system in a plurality of colors, and wherein the discrete elements of the image have been coded by a color function related to system behavior at the two preselected time points to have a color hue of one of said plurality of colors indicative of the system wash-out behavior.	1. A set of at least two calibration maps for use in monitoring a system in which fluid flows and which is characterized by a change in a system parameter with time in space as a function of two variables related to system wash-in and system wash-out behavior at two time intervals after a system event, each map based on different time intervals and depicting in two or three dimensions an image of the two variables ranging from a minimum to a maximum wherein the discrete elements of the image have a color hue of one of a plurality of colors indicative of system wash-out behavior and a color intensity indicative of system wash-in behavior. 7. A set of at least two images depicting in two or three dimensions a location in a system in which fluid flows and which is characterized at said

	location by a change in a system parameter as a function of two variables related to system wash-in behavior at a first time interval and system wash-out behavior at a second time interval after a system event, the discrete elements of the image having a color hue of one of a plurality of colors indicative of system wash-out behavior and a color intensity indicative of system wash-in behavior, with the time intervals for the at least two images being different.

In view of above literal comparison, it is obvious that both the instant application and the '327 patent essentially claim patentably the same invention. To the extent that the instant claim is broader and therefore generic to the patented claims [species], *In re Goodman* 29 USPQ 2d 2010 CAFC 1993, states that a generic claim cannot be issued without a terminal disclaimer, if a species claim has been previously been patented.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action'.

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 88-90 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 7 of Degani ('327).

Degani discloses the color coded image including the subject matters recited in independent claims 1 and 7 except: said system comprises human tissue; said system comprises human breast tissue; said system comprises two breasts.

In view of the disclosure of Degani, it would have been obvious to one having ordinary skill in the art at the time the invention was made to apply the generic invention of Degani to a specific system comprising human breast tissue wherein said system comprises two breasts. It has been held that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

5. Claim 91 is rejected under 35 U.S.C. 103(a) as being unpatentable over Degani ('327) in view of Cline et al. (U.S. Pat. No. 5,204,625).

Degani discloses the color coded image including the subject matters recited in independent claim 87 except: said system event is defined by injection of a tracer into the fluid.

Cline et al. discloses a technique for reconstructing a 3D image of a human body structure using flow sensitive data arrays (Abstract), and teach: a system event defined by injection of a tracer into the fluid (col. 1, lines 31-34).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate the teaching of Cline et al. into the invention of Degani so that the location of, for example, blood vessels with in an internal body structure can be identified in radiographic angiography (Cline et al., col. 1, lines 31-34).

6. Claims 102 and 103 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 7 of Degani ('327) in view of Cline et al. (U.S. Pat. No. 5,204,625).

Table 2

10/812,852	**U.S. 6,553,327**
102. A color coded image for use in evaluating a lesion in the breast of a subject body in which blood flows and in which a contrast agent has been injected into the blood and which is characterized by a change in the concentration of the contrast agent in the breast with time in space ms a function of the contract agent wash-in and wash-out behavior at two time intervals after injection of the contrast agent, said image depicting in two or three dimensions an image correlated with the said behavior, and wherein the discrete elements of the image have been color coded by a color function to have a color hue of one of a plurality of colors indicative of the contrast agent wash-out behavior and have been coded by an intensity function to have a color intensity indicative of the contrast agent wash-in behavior. 103. The color coded image of claim 102 wherein said behaviors are determined by two variables, K and v, wherein K defines microvascular permeability and v defines the fraction of extracellular volume which estimates the amount of free space in the	1. A set of at least two calibration maps for use in monitoring a system in which fluid flows and which is characterized by a change in a system parameter with time in space as a function of two variables related to system wash-in and system wash-out behavior at two time intervals after a system event, each map based on different time intervals and depicting in two or three dimensions an image of the two variables ranging from a minimum to a maximum wherein the discrete elements of the image have a color hue of one of a plurality of colors indicative of system wash-out behavior and a color intensity indicative of system wash-in behavior. 7. A set of at least two images depicting in two or three dimensions a location in a system in which fluid flows and which is characterized at said location by a change in a system parameter as a function of two variables related to system wash-in behavior at a first time interval and system wash-out behavior at a second time interval after a

breast.	system event, the discrete elements of the image having a color hue of one of a plurality of colors indicative of system wash-out behavior and a color intensity indicative of system wash-in behavior, with the time intervals for the at least two images being different.

The subject matters recited in claims 102 and 103 of the instant application are obvious equivalents of that recited in claims 1 and 7 of '327 except: said color coded image for use in evaluating a lesion in the breast of a subject body in which blood flows and in which a contrast agent has been injected.

Cline et al. discloses a technique for reconstructing a 3D image of a human body structure using flow sensitive data arrays (Abstract), and teach: a system event defined by injection of a tracer into the fluid (col. 1, lines 31-34).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate the teaching of Cline et al. into the invention of Degani so that the location of, for example, blood vessels with in an internal body structure can be identified in radiographic angiography (Cline et al., col. 1, lines 31-34).

In view of the teaching of Degani and Cline et al., it would have been obvious to one having ordinary skill in the art at the time the invention was made to apply the color coded image to a specific system comprising human breast tissue. It has been held that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of

performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

7. Claims 120-126 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 7 and 8 of Degani ('327) in view of Cline et al. (U.S. Pat. No. 5,204,625).

Table 3

10/812,852	**U.S. 6,553,327**
120. A method for generating a color-coded image of a tissue of a human patient, comprising: selecting a plurality of time points which define at least a first time interval after a system event and a second time interval after the system event; obtaining an MRI image of a location in a tissue of a human patient at each of the plurality of time points; processing the MRI images, and based thereon, generating a color coded image of the location in the tissue, the color coded image having a plurality of discrete elements, the discrete elements of the image having a color hue indicative of wash-out behavior in the tissue during the second time interval and a color intensity indicative of wash-in behavior in the tissue during the first time interval. 121. The method of claim 120, wherein the step of generating the color coded image further comprises displaying said color coded image on a display screen. 122. The method of claim 120, wherein the	1. A set of at least two calibration maps for use in monitoring a system in which fluid flows and which is characterized by a change in a system parameter with time in space as a function of two variables related to system wash-in and system wash-out behavior at two time intervals after a system event, each map based on different time intervals and depicting in two or three dimensions an image of the two variables ranging from a minimum to a maximum wherein the discrete elements of the image have a color hue of one of a plurality of colors indicative of system wash-out behavior and a color intensity indicative of system wash-in behavior. 2. A calibration map according to claim 1 wherein the image is a display on a monitor. 7. A set of at least two images depicting in two or three dimensions a location in a system in which fluid flows and which is characterized at said location by a change in a system

tissue is female human breast tissue. 123. The method of claim 120, wherein the system event is an injection of a contrast agent into the human patient. 124. The method of claim 120, wherein the second time interval is after the first time interval. 125. The method of claim 120, wherein the time points include a first time point, a second time point subsequent to the first time point, and a third time point subsequent to the second time point, the first time interval being between the first and second time points and the second time interval being between the second and the third time points. 126. The method of claim 120, further comprising altering the time points to redefine the first and second time intervals, and repeating the obtaining and processing steps.	parameter as a function of two variables related to system wash-in behavior at a first time interval and system wash-out behavior at a second time interval after a system event, the discrete elements of the image having a color hue of one of a plurality of colors indicative of system wash-out behavior and a color intensity indicative of system wash-in behavior, with the time intervals for the at least two images being different. 8. The image of claim 7 as a display on a monitor.

Regarding claim 120, the subject matters recited in this claim are obvious equivalents of that recited in claims 1 and 7 of '327 except: said color coded image for use in evaluating a tissue of a human patient; generating color coded images based on MRI images of a location in a tissue of said human patient.

Cline et al. discloses a technique for reconstructing a 3D image of a human body structure using flow sensitive data arrays (Abstract), and teach: generating color coded images based on MRI images of a location in a tissue of a human patient (col. 6, lines 25-35; col. 13, lines 16-22; col. 14, lines 6-20).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate the teaching of Cline et al. into the invention of Degani in order to provide an efficient mechanism for producing a high quality feature map of human body structure and tissue classifications with minimum amount of intervention by an operator (col. 14, lines 52-59).

Regarding claim 121, Degani teaches the claimed invention (Degani, claims 2 and 8).

Regarding claim 122, Degani teaches the claimed invention except: said tissue is female human breast tissue.

In view of the teaching of Degani and Cline et al., it would have been obvious to one having ordinary skill in the art at the time the invention was made to apply the color coded image to a specific system comprising female human breast tissue. It has been held that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Regarding claim 123, Degani teaches the claimed invention except: wherein the system event is an injection of a contrast agent into the human patient.

The teaching of Cline et al. includes: a system event defined by injection of a tracer into the fluid (col. 1, lines 31-34).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate the teaching of Cline et al. into the invention of Degani so that the location of, for example, blood vessels with in an internal body structure can be identified in radiographic angiography (Cline et al., col. 1, lines 31-34).

Regarding claim 124, Degani teaches implicitly the claimed invention (Claims 1 and 7).

Regarding claim 125, Degani teaches the claimed invention except: wherein the time points include a first time point, a second time point subsequent to the first time point, and a third time point subsequent to the second time point, the first time interval being between the first and second time points and the second time interval being between the second and the third time points.

The teaching of Cline et al. includes: wherein the time points include a first time point, a second time point subsequent to the first time point, and a third time point subsequent to the second time point, the first time interval being between the first and second time points and the second time interval being between the second and the third time points (col. 6, lines 25-35; col. 13, lines 16-22; col. 14, lines 6-20).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate the teaching of Cline et al. into the invention of Degani in order to provide an efficient mechanism for producing a high quality feature

map of human body structure and tissue classifications with minimum amount of intervention by an operator (col. 14, lines 52-59).

Regarding claim 126, Degani teaches the claimed invention except: altering the time points to redefine the first and second time intervals, and repeating the obtaining and processing steps. However, in view of the teaching of Degani and Cline et al., it would have been obvious to one having ordinary skill in the art at the time the invention was made to rearrange the time points in order to redefine the first and second time intervals, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse,* 86 USPQ 70.

Allowable Subject Matter

8. Claims 92-101 are allowed.

Reasons for Allowance

9. The following is an examiner's statement of reasons for allowance:

The primary reason for the allowance of claims 92-96 is the inclusion of the limitations of the discrete elements of the image have been coded by an intensity function related to system behavior before the system event and the first of the two selected time points to have a color intensity indicative of the system wash-in behavior. It is these limitations found in each of the claims, as they are claimed in the combination that have not been found, taught or suggested by the prior art of record, which make these claims allowable over the prior art.

The primary reason for the allowance of claims 97-101 is the inclusion of the limitations of the discrete elements of the image have been coded by a color function

related to system behavior at the two preselected time points to have a color hue of one of said plurality of colors indicative of the system wash-out behavior and have been coded by an intensity function related to system behavior at the system event and the first of the two selected time points to have a color intensity indicative of the system wash-in behavior. It is these limitations found in each of the claims, as they are claimed in the combination that have not been found, taught or suggested by the prior art of record, which make these claims allowable over the prior art.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Contact Information

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Xiuqin Sun whose telephone number is (571)272-2280. The examiner can normally be reached on 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Barlow can be reached on (571)272-2269. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Xiuqin Sun
Examiner
Art Unit 2863

XS
April 13, 2006

BRYAN BUI
PRIMARY EXAMINER